

Atty Dkt No. CARL3003/REF
USSN: 09/868,243
PATENT

ACCOMPANYING DOCUMENTS

Accompanying this Amendment are the following documents: (a) a Petition for Extension of Time to respond to the Office Action; and (b) an Associate Power of Attorney.

AMENDMENT

In the Claims:

Please amend claims 1-4 as follows:

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1. (Amended) An oral vaccine composition against diarrhea caused by enterotoxigenic *E. coli*, which comprises at least three different types of colonization factor antigens (CFAs) ^{of said *E. coli*} selected from the group consisting of CFA I, CFA II (CS1, CS2 and CS3) and CFA IV (CS4, CS5 and CS6), on killed *E. coli* bacteria lacking the gene encoding the heat labile enterotoxin (LT), together with the B-subunit of cholera toxin (CTB), and a physiologically acceptable vehicle, ^{wherein} ~~which vaccine composition does not contain~~ heat stable enterotoxin (ST) ^{of said *E. coli* is removed from said antigens is present.}
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2. (Amended) ^{The} ~~An~~ oral vaccine according to claim 1, wherein the vaccine comprises at least 100 µg of each type of CFA, and at least 0.5 mg of CTB, and the vehicle is a buffer solution.
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3. (Amended) ^{The} ~~An~~ oral vaccine according to claim 2, wherein the vaccine comprises 100 to 300 µg of each type of CFA, and 0.5 to 2.0 mg of CTB.
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4. (Amended) ^{The} ~~An~~ oral vaccine according to claim 3, wherein the vaccine comprises 200 µg of CFA/I, 200 µg of CS1, 150 µg of CS2, 200 µg of

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CS4, 150 μ g of CS5, and 1.0 mg of CTB, and the buffer solution is phosphate buffered saline solution.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-4 have been amended as follows.

1. (Amended) [Oral] An oral vaccine composition against diarrhea caused by enterotoxigenic *E. coli* [caused diarrhea in humans], which comprises [a defined amount of] at least three different types of colonization factor antigens (CFAs) selected from the group consisting of CFA I, CFA II (CS1, CS2 and CS3) and CFA IV (CS4, CS5 and CS6), on killed *E. coli* bacteria lacking the gene encoding the heat labile [(LT)] enterotoxin (LT), together with [a defined amount of] the B-subunit of cholera toxin (CTB), and [an] a physiologically acceptable vehicle, which vaccine composition [is purified from possible] does not contain heat stable enterotoxin (ST).

2. (Amended) [Oral] An oral vaccine according to claim 1, wherein the [defined amount of different types of CFAs is for each type of CFA] vaccine comprises at least 100 μg of each type of CFA, and [the defined amount] at least 0.5 mg of CTB [is at least 0.5 mg], and the vehicle is a [physiologically acceptable] buffer solution.

3. (Amended) [Oral] An oral vaccine according to claim 2, wherein the [defined amount of different types of CFAs is for each type of CFA] vaccine comprises 100 to 300 μg of each type of CFA, and [the defined amount of CTB is] 0.5 to 2.0 mg of CTB.

4. (Amended) [Oral] An oral vaccine according to claim 3, wherein the [defined amount of different types of CFAs are] vaccine comprises 200 μg of CFA/I, 200 μg of CS1, 150 μg of CS2, 200 μg of CS4, [and] 150 μg of CS5, and

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